U.S. FOOD & DRUG ADMINISTRATION

FDA ELECTRONIC SUBMISSIONS GATEWAY

eCTD

The FDA Electronic Submissions Gateway (ESG) is the central transmission point for sending information electronically to FDA. The ESG does not open or review submissions. It receives submissions, acknowledges receipt, routes them to the proper FDA center or office, and notifies that center or office of delivery.

Submission types

The FDA ESG supports the receipt of guidance-compliant electronic regulatory submissions to the Center for Biologics Evaluation and Research (CBER) and the Center for Drug Evaluation and Research (CDER). The FDA ESG also supports the receipt of reports and attachments for many other FDA offices and centers. FDA is continually expanding the list of electronic regulatory submissions that can be received by the ESG.

Submission requirements

Beginning **May 5, 2017,** many submissions to CDER/CBER will be required to use the Electronic Common Technical Document (eCTD) format. (The deadline is **May 5, 2018,** for commercial INDs.) Submissions that fall under the eCTD requirement and are 10 GB or less in size must be submitted via the FDA ESG as of the applicable date. For more information on these requirements, see www.fda.gov/ectd.

Submission options

FDA ESG options include the following:

- An AS2 Gateway-to-Gateway Connection
- WebTrader software installed on submitter's computer
- WebTrader Hosted Solution, which allows users to make submissions from almost any Web browser.

Getting started

The first step to submitting electronically through ESG is to request a test account. Refer to the FDA ESG User Guide, available at www.fda.gov/esg, for information on how to submit the registration request. Setting up an ESG account is a multi-step process and should be started well before you intend to make your first electronic submission.

The eCTD is CDER and CBER's standard format for electronic regulatory submissions. Beginning **May 5, 2017,** the following submission types must be submitted in eCTD format: **NDA, ANDA, BLA** (with some exceptions), and **Master Files,** along with amendments, supplements, and reports for these submission types. **Commercial IND** submissions must be submitted in eCTD format beginning **May 5, 2018.** Submissions that do not adhere to the requirements stated in the eCTD Guidance will not be filed or received.

Additional information

For more information, please visit www.fda.gov/ectd

If you have questions for CDER, please contact **CDER ESUB** at esub@fda.hhs.gov

If you have questions for CBER, please contact **CBER ESUB** at esubprep@fda.hhs.gov

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES/U.S. FOOD & DRUG ADMINISTRATION
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